UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION, THIS DOCUMENT RELATES TO: *Meijer, Inc., et al. v. Ranbaxy, Inc., et al.*, No 15-cv-11828 (D. Mass.) *Meijer, Inc., et al. v. Ranbaxy, Inc., et al.*, No 18-cv-12129 (D. Mass.) *Cesar Castillo, Inc. v. Ranbaxy, Inc., et al.*, No. 18-cv-06126 (E.D.N.Y.)	MDL No. 19-md-02878-NMG

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE CONSOLIDATED DIRECT PURCHASER COMPLAINT

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Defendants Ranbaxy, Inc. and Sun Pharmaceutical Industries Ltd. (collectively "Ranbaxy") move to dismiss the Consolidated Direct Purchaser Complaint, No. 19-md-2878, Dkt. 20 ("Compl."), for failure to state a claim on which relief may be granted.[1]

INTRODUCTION

Plaintiffs are not the FDA. That fact compels dismissal of their suit. *Nothing* Ranbaxy allegedly did could possibly amount to a violation of *any* law *unless* Plaintiffs prove that Ranbaxy violated the Federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiffs admit this; they concede, as they must, that every act described in their hundred-page Complaint would be perfectly lawful unless they can show that Ranbaxy perpetrated a "fraud on the FDA" by violating the FDCA's disclosure requirements. That concession is fatal, for it proves that this suit is unabashedly one "for the enforcement" of the FDCA. 21 U.S.C. § 337(a). Plaintiffs therefore cannot maintain it, because "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with its terms. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). The entire Complaint must be dismissed as a result.

Ranbaxy acknowledges that the Court previously considered this argument and was ultimately unpersuaded. *See Meijer, Inc. v. Ranbaxy Inc.*, No. 1:15-cv-11828-NMG (D. Mass. Sept. 7, 2016) ("*Meijer I*"), Dkt. 80 at 19. Nevertheless, Ranbaxy respectfully submits that present circumstances warrant a fresh look. As the Court explained when it certified this issue for interlocutory appeal, "this is the first time a party has brought antitrust claims predicated on fraud on the FDA," and the permissibility of such claims raises "[a] substantial ground for difference of opinion." *Meijer I*, Dkt. 124 at 7. The First Circuit spent 21 months considering Ranbaxy's application before declining to accept the appeal. But that was before *Meijer I* was consolidated

[1] The Complaint also names as defendants Ranbaxy Laboratories Limited and Ranbaxy USA Inc. These entities no longer exist, Compl. ¶¶ 16, 18, and should therefore be dismissed. *See Meijer I*, Dkt. 52 at 8, 54.

into a Multi-District Litigation. The stakes of this critically important, "controlling" question are thus significantly higher now than than they were previously. *Id.* at 6. Given that the Court can answer this question "with minimal review of the factual record," *id.*, the Court would be amply justified in taking it up once more.

The entire Complaint also fails because *Noerr-Pennington* confers "absolute immunity," from both antitrust and RICO liability, on parties who "urg[e] . . . governmental action" that results in an "anticompetitive restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988). Plaintiffs' inability to allege proximate causation is yet another dispositive defect—and one the present Complaint highlights by adding allegations about a new drug (Nexium) that was not at issue in *Meijer I*. Finally, Plaintiffs' RICO claims fail because Ranbaxy cannot have committed a predicate offense; wire and mail fraud are inapposite because all agree that Ranbaxy did not deprive the FDA of any property. This argument was not before the Court in *Meijer I*.

BACKGROUND

Given the Court's familiarity with this case, Ranbaxy offers the following abbreviated background. *See Meijer I*, Dkt. 22 at 3-10 (providing more extended background).

A. Regulatory Background

The FDCA empowers the FDA to regulate and approve prescription drugs. *See* 21 U.S.C. § 301 *et seq.* In 1984, Congress amended the FDCA by passing the "Hatch-Waxman Act," which aimed to reduce prescription drug prices by making it easier for generic drugs to come to market.

To that end, Hatch-Waxman first streamlined the FDA approval process by removing the need for manufacturers to conduct new clinical trials before launching generic versions of previously approved branded drugs. *See id.* § 355(d)(7). A generic manufacturer can instead submit an "Abbreviated" New Drug Application ("ANDA") demonstrating that its proposed generic has the same therapeutically active ingredient, and releases it at the same rate and to the

same extent, as an approved drug. *See id.* § 355(j)(2)(A)(vii). The generic applicant may then rely on the FDA's prior determination that the equivalent branded drug is safe and effective. *Id.*

Hatch-Waxman also created incentives for generic manufacturers to challenge brand manufacturers' patents, which can block generics from coming to market even after they are approved. Hatch-Waxman allows ANDA filers to declare that any brand patents that cover the drug in question are either invalid, unenforceable, or will not be infringed by the generic. *See id.* This declaration is called a "Paragraph IV certification." Hatch-Waxman provides that if a manufacturer's ANDA contains a Paragraph IV certification and is the first ANDA for the relevant generic to be deemed "substantially complete" by the FDA, then the manufacturer becomes eligible to obtain the right to block most other generics from entering the market until 180 days after the generic itself enters the market. *See id.* § 355(j)(5)(B)(iv). Until this 180-day period expires, the FDA is barred from approving any other ANDAs for the same drug; the only generic that can compete is an "authorized generic" sold by the brand manufacturer. *See id.*

A generic manufacturer that is eligible for exclusivity, however, can forfeit its eligibility in certain circumstances. Most relevant here, an ANDA must obtain "tentative approval" from the FDA within 30 months of being declared "substantially complete." *Id.* § 355(j)(5)(D)(i)(IV). "Tentative approval" means that an ANDA meets all of the statutory criteria for final approval, but cannot come to market due to pending Hatch-Waxman litigation, or because a different manufacturer has a valid patent or an exclusivity period. *Id.* § 355(j)(5)(B)(iv)(II)(dd)(AA).[2]

Given the stakes involved, Congress knew that regulated parties might be tempted to lie to the FDA. The FDCA therefore prohibits fraud on the FDA, *see id.* § 331, and it empowers the FDA to identify, punish, and deter such fraud, *see id.* §§ 372, 332-334. But Congress rejected a

[2] There is an exception if a generic exceeds 30 months because of "a change in or a review of the requirements for approval of the application imposed after . . . the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV).

scheme in which anyone injured by fraud on the FDA would be entitled to sue wrongdoers in court. Instead, the FDCA declares that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." *Id.* § 337(a). Section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. *Buckman*, 531 U.S. at 349 n.4.

B. Factual Allegations[3]

Ranbaxy is an India-based pharmaceutical company. This case is about Ranbaxy's alleged effort to defraud the FDA while developing generic versions of three drugs: Diovan, Valcyte, and Nexium. Compl. ¶¶ 305-366. Ranbaxy submitted the first substantially complete ANDA for each such drug in 2004 (Diovan) and 2005 (Valcyte and Nexium). *Id.* ¶¶ 77, 80. It then obtained tentative approval for each drug in 2007 (Diovan) and 2008 (Valcyte and Nexium)—and with it, entitlement to a 180-day exclusivity period. *Id.* ¶¶ 143, 157, 226.[4] Plaintiffs conclusorily allege that these results are attributable to Ranbaxy's fraud on the FDA, *e.g.*, *id.*, although as discussed below, the FDA has publicly stated otherwise, as the documents cited in the Complaint establish.

Plaintiffs allegedly purchased brand or generic versions of the drugs at issue here directly from manufacturers. *See id.* ¶¶ 13-14. They seek to represent classes of direct purchasers. *Id.* ¶ 296. Plaintiffs claim that absent Ranbaxy's alleged FDCA violations that led it to acquire 180-day exclusivity, other manufacturers would have launched generic versions of these drugs during each class period, and Plaintiffs would have paid less as a result. *Id.* ¶¶ 194-242. Plaintiffs seek recovery under the Sherman Act, 15 U.S.C. § 2, and the RICO Act, 18 U.S.C. § 1962(c). *Id.* ¶ 21.

[3] Ranbaxy merely assumes the truth of Plaintiffs' allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

[4] Ranbaxy took over 30 months to obtain tentative approval for Diovan, but such delay was "caused by a change in . . . the requirements for approval of the application," so the FDA allowed Ranbaxy to keep exclusivity. *Id.* ¶ 208.

The Complaint focuses on alleged misrepresentations Ranbaxy made to the FDA between 2006 and 2008, *id.* ¶¶ 94-154, 184, but it makes clear that the FDA thoroughly investigated and made a complete response to Ranbaxy's actual and suspected FDCA violations. Indeed, following several years of inspections, investigations, warning letters, and compliance holds, *see id.* ¶¶ 90, 91, 93, 162, 164, by 2009 the FDA was fully aware that Ranbaxy had in the past "submitted untrue statements of material fact in abbreviated and new drug applications filed with the agency," *id.* ¶ 163. Several more years of investigation and sanction followed. Among other things, in 2013 Ranbaxy entered into a civil settlement and criminal plea agreement with the Federal Government in which Ranbaxy paid a fine and penalty for making false statements to the FDA in regard to certain ANDAs. *Id.* ¶¶ 182-183. In addition, a critically important event occurred on January 25, 2012, when Ranbaxy and the FDA entered into a consent decree, which ultimately allowed Ranbaxy to maintain its first-to-file ANDAs for generic Diovan, Valcyte, and Nexium. *Id.* ¶¶ 180, 173. Indeed, although Ranbaxy was forced to give up its exclusivities for three ***other*** ANDAs, the FDA allowed Ranbaxy to keep its 180-day exclusivities for Diovan, Valcyte, and Nexium. *Id.* ¶¶179-180. Plaintiffs make no allegation that these decisions were in any way induced by fraud.

Those 2012 decisions reflected the FDA's conclusions—after a comprehensive audit—that even if Ranbaxy had committed misconduct with respect to ***other*** ANDAs, its Diovan, Valcyte, and Nexium ANDAs contained no "untrue statements or data irregularities" and were in fact substantially complete when filed. *See id.* ¶¶ 180, 205, 219-220, 233.[5] Those decisions also reflected the FDA's view that the public health, regulatory, and law-enforcement interests at stake would be best served by allowing Ranbaxy to keep its Diovan, Valcyte, and Nexium exclusivities.

[5] *See also* Decl. of Laurence Schoen ("Schoen Decl."), Ex. 1 (letter from FDA to Ranbaxy dated July 6, 2012) (Diovan); Schoen Decl., Ex. 2 (Letter from FDA to Ranbaxy dated Aug. 10, 2012) (Valcyte); Ex. 3 (letter from FDA to Ranbaxy dated November 4, 2014) (Nexium). These letters may be judicially noticed. Fed. R. Evid. 201(b).

The FDA granted final approval to Ranbaxy's generic Diovan ANDA on June 26, 2014, and Ranbaxy began sales that July. *Id.* ¶¶ 208, 210. Plaintiffs do not allege that fraud played any role in the FDA's grant of final approval to the generic Diovan ANDA. In 2014, however, the FDA realized that it had "erred in tentatively approving" the Valcyte and Nexium ANDAs back in 2008, at a time when FDA knew that "'the compliance status of the facilities referenced in the ANDA[s] at the time the ANDA[s] [were] granted tentative approval was inadequate to support approval or tentative approval.'" Compl. ¶¶ 222, 238. As the United States District Court for the District of Columbia noted in a related litigation: "the FDA admits that granting tentative approval to [Ranbaxy's Valcyte and Nexium ANDAs] was an error, which [it] attribute[s] to a breakdown in communications between CDER, the compliance inspection component of the FDA, and OGD, the approval component of the FDA." *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 190 (D.D.C. 2015). On November 4, 2014, the FDA decided to correct its own error by rescinding tentative approval for Ranbaxy's generic Valcyte and Nexium ANDAs and also its exclusivity for Valcyte. Compl. ¶¶ 222, 238; *see also* Schoen Decl., Ex. 4. The FDA revoked Ranbaxy's exclusivity for Nexium on January 26, 2015. *Id.* ¶ 239. Following these developments, other generic manufacturers entered both markets. Notably, however, Plaintiffs do not allege that any other manufacturer not blocked by a patent had obtained tentative approval for generic Valcyte or Nexium during the time Ranbaxy possessed exclusivity. *See id.* ¶¶ 223-224, 239-240.

C. Procedural History

The first case in this MDL, *Meijer I*, was filed in 2015. Ranbaxy filed a motion to dismiss, which Magistrate Judge Kelly recommended denying. *Meijer I*, Dkt. 52. The Magistrate reasoned that the claims in *Meijer I* were not precluded by the FDCA because they arose under federal rather than state law, and thus "*Buckman*'s analysis does not directly resolve the matter." *Id.* at 20. This Court adopted that recommendation without opinion on September 7, 2016. *Id.* Dkt. 80. But

recognizing that Defendants had raised a difficult, dispositive, and purely legal question of first impression, the Court certified its order for interlocutory appeal. *See id.* Dkt. 124, at 9. On December 28, 2018, the First Circuit declined to hear the appeal on an interlocutory basis.

The nature of this case has changed dramatically since 2016. The plaintiffs in *Meijer I* filed a second complaint asserting claims based on a third drug, Nexium, and other plaintiffs filed suit against Ranbaxy in additional circuits. These cases were subsequently consolidated in this Court by the Judicial Panel on Multidistrict Litigation. *See* No. 19-md-2878, Dkt. 5.

ARGUMENT

The Complaint fails entirely because it is barred by the FDCA and by *Noerr-Pennington*, as well as for lack of proximate causation. And the RICO claims fail for lack of a predicate offense.

I. PLAINTIFFS' SUIT IS BARRED BY THE FDCA.

Congress has explicitly barred private parties from bringing suits like this one. The express terms of the FDCA and *Buckman* establish that a private party cannot maintain a suit if a defendant's conduct would not be unlawful absent proof that the defendant violated the FDCA. That rule fits this case to a T. Although Plaintiffs assert claims under the Sherman Act and the RICO Act, there is no dispute that if Ranbaxy did not violate the FDCA, Ranbaxy could not have violated those statutes, either. Because Ranbaxy's liability under the Sherman Act and RICO rises and falls entirely on whether Ranbaxy violated the FDCA, this suit must be dismissed in full.

A. A Private-Party Suit Is Barred If a Defendant's Conduct Would Not Be Unlawful Absent Proof that It Violated the FDCA.

Congress knew that regulated entities would be tempted to lie to the FDA. The FDCA therefore "amply empowers the FDA to punish and deter fraud against the Administration," through "a variety of enforcement options." *Buckman*, 531 U.S. at 348-49. But, critically, the FDCA declares that "all such proceedings for the enforcement, or to restrain violations, of this

chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. *Buckman*, 531 U.S. at 349 n.4.

The Supreme Court explained the operation of §337(a) in *Buckman*. In that case, private parties sued a consulting company for making fraudulent statements to the FDA in order to help a manufacturer gain approval to market orthopedic bone screws. *Id.* at 343. The plaintiffs styled their complaint as arising under state tort law. *Id.* at 343, 346-47. The Supreme Court, however, looked through the label of their pleadings to the substance of their claims and held that the FDCA barred the suit. *Id.* at 353. The dispositive issue, the Court explained, was that "the existence of these federal enactments"—*i.e.*, the FDCA and its disclosure requirements—"is a critical element in [the plaintiffs'] case." *Id.* In other words, state tort law, standing alone—without referencing the FDCA—could not have rendered the defendant's conduct unlawful. Hence, plaintiffs' theory of liability "exist[ed] solely by virtue of the FDCA disclosure requirements." *Id.* For that reason the suit was really one "for the enforcement" of the FDCA within the meaning of §337(a)—which meant that it was barred, because §337(a) provides "clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Id.* at 352.

Buckman therefore stands for a clear rule. A private-party suit is barred if a defendant's conduct could not be deemed unlawful absent proof that it violated the FDCA. When that condition is met, the FDCA serves as a "critical element" in the plaintiff's case, *id.* at 353, which means that the suit is really one "for the enforcement" of the FDCA within the meaning of §337(a). And that means it must be dismissed. *Id.* Private-party suits fitting that description cannot proceed because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350.

The Supreme Court's later decision in *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), confirms the above understanding of *Buckman*. In *POM*, the plaintiff alleged that Coca-Cola violated the Lanham Act by affixing a misleading label to one of its juice products. *Id.* at 105-06. Crucially, unlike in *Buckman*, in *POM* the plaintiff did not allege that the defendant's conduct violated the FDCA—and in fact the Court took for granted that Coca-Cola had *not* violated the FDCA. *See id.* at 111. For that reason, unlike in *Buckman*, in *POM* the plaintiff's suit could not be described as one "for the enforcement" of the FDCA, and so §337(a) was no obstacle. *See id.* at 116-17. Rather, the question was whether Coca-Cola's *compliance* with the FDCA rendered it immune from liability under the Lanham Act. *Id.* at 119. Unsurprisingly, the Supreme Court said no, and so the plaintiff's Lanham Act claim was allowed to proceed. *Id.* at 119-20.

Far from undermining Ranbaxy's argument, *POM* confirms that a private suit must be dismissed any time the FDCA is a "critical element" of the plaintiff's case, regardless of whether the suit arises under state or federal law. Indeed, the only thing *POM* held is that a defendant can be sued under the Lanham Act ***if*** the defendant did ***not*** violate the FDCA. But if the plaintiff in *POM* ***had*** alleged that Coca-Cola had violated the FDCA—and was liable under the Lanham Act ***only because*** of that violation—there is no question that §337(a) would have barred the suit. In fact, *POM* itself cited §337 to reaffirm that "[p]rivate parties may not bring enforcement suits" for violations of the FDCA. 573 U.S. at 109. That *POM* reiterated this basic point in the context of a federal-law suit confirms that the *Buckman* rule applies with full force regardless of whether a private suit arises under state or federal law. Again, that is because—as *Buckman* explained—such private suits "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350.

This case is nothing like *POM*, and everything like *Buckman*, because—as explained below—there is no disputing that Ranbaxy's conduct cannot be deemed a Sherman Act or RICO Act violation *unless* it violated the FDCA.

B. Ranbaxy's Conduct Would Be Perfectly Lawful Unless Plaintiffs Prove that Ranbaxy Violated the FDCA.

As explained above, §337(a) requires dismissal of any private-party suit in which the FDCA serves as a "critical element" in the plaintiff's case—that is, any suit in which the defendant's conduct could not be deemed unlawful unless the plaintiff proves that the defendant violated the FDCA. That is the case here, because Ranbaxy's liability under the Sherman Act and the RICO Act requires the Plaintiffs to prove that Ranbaxy violated the FDCA.

This point is straightforward and uncontroversial. The FDA granted Ranbaxy the right to exclude most of its competitors for 180 days—but standing alone, such conduct could not violate the Sherman Act, because it is black-letter law that even anticompetitive conduct is immune from antitrust scrutiny if such conduct is approved by a federal agency. *See Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 275 (2007); *Gordon v. New York Stock Exch., Inc.*, 422 U.S. 659, 682 (1975); *United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 729-30 (1975). Nor could private plaintiffs invoke RICO's general antifraud provisions to second-guess the FDA's judgment that a regulated party's representations entitled it to exclusivity under the specific, non-privately-enforceable provisions of the FDCA. *See Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976) ("'[A] specific statute will not be controlled or nullified by a general one.'").

Plaintiffs do not suggest otherwise; they do not argue that a drug manufacturer could be sued under the Sherman Act or RICO merely for obtaining FDA authorization to exclude its rivals for 180 days. Indeed, the Complaint acknowledges that "[t]he Hatch-Waxman Amendments empower the holder of a *lawfully acquired* first-to-file, 180-day exclusivity to exclude all other

would-be generics from gaining ANDA approval of their applications until expiration of the exclusivity." Compl. ¶ 260 (emphasis added). The Complaint's entire theory is that Ranbaxy's conduct qualifies as unlawful because—and *only* because—Ranbaxy allegedly acquired exclusivity through means that violated the FDCA. *E.g.*, *id.* ¶¶ 308, 319, 359.

Thus, Plaintiffs' entire case hinges on the proposition that "Ranbaxy engaged in a knowing, direct fraud against a governmental entity (the FDA), which was empowered to grant a period of market exclusivity." *Id.* ¶¶ 312, 323, 363. And because proving fraud on the FDA requires proving a violation of the FDCA, it follows that the FDCA serves as a "critical element" in the Plaintiffs' case, just as in *Buckman*. 531 U.S. at 353. Like the plaintiffs in *Buckman*, Plaintiffs here would have no case if the FDCA's disclosure requirements were not on the books. That means this lawsuit is nothing more than a "proceeding[] for the enforcement" of the FDCA. 21 U.S.C. § 337(a). Plaintiffs are therefore not permitted to maintain it. *Id.*

C. Allowing Plaintiffs' Suit to Proceed Would Inflict All of the Harms that Required Dismissal in *Buckman*.

The text of §337(a) and the holding of *Buckman* are enough to compel dismissal of Plaintiffs' Complaint. But *Buckman* also discussed a number of practical concerns that arise when private parties bring suit to enforce the FDCA. Those concerns apply with full force here, and without exception they demonstrate why dismissal is necessary.

First, *Buckman* deemed dismissal necessary because the FDA's power "to deter fraud against the Administration . . . is used by the Administration to achieve a somewhat delicate balance of statutory objectives," and this balance "can be skewed by allowing fraud-on-the-FDA claims" by private plaintiffs. *Buckman*, 531 U.S. at 348. Plaintiffs' suit here poses exactly the same risk of "skewing" the balance the FDA was required to strike in deciding what sort of response was appropriate in light of Ranbaxy's actual and alleged FDCA violations. It makes no

difference that in *Buckman* the plaintiffs sought to interject themselves under the guise of state tort law, whereas here Plaintiffs seek to interject themselves under the guise of the Sherman Act and RICO. The problem is the same because all such plaintiffs are attempting to second-guess the FDA's pursuit of the "difficult (and often competing) objectives" involved in administering the FDCA. *Id.* at 349. Hence, this suit illustrates *Buckman*'s teaching that private-party "fraud-on-the-FDA claims *inevitably* conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350 (emphasis added).

Second, *Buckman* emphasized that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants." *Id.* at 350. Suits like this one create a similar dilemma, because from now on regulated parties will need to contend not only with the FDA (as §337(a) envisions), but also with a potentially limitless number of private plaintiffs armed with the entire U.S. Code. Requiring regulated parties to navigate the FDA's complex regulatory regime in the shadow of so many potential plaintiffs would undoubtedly impose "burdens not contemplated by Congress in enacting the FDCA." *Id.* It would also defeat the "flexibility" Congress gave the FDA to ensure that responses to FDCA violations are genuinely in the public interest. *Id.* at 349.

Finally, *Buckman* stressed that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.* at 351. Cases like this one create similar bad incentives, because they too allow private plaintiffs, juries, and judges to look over the FDA's shoulder, deciding for themselves whether an entity's representations were sufficiently

forthcoming to justify the FDA's grant of exclusivity. And, again, it makes no difference that here Plaintiffs are seeking to enforce the FDCA under the guise of other federal statutes, whereas in *Buckman* the plaintiffs sought to enforce the FDCA under the guise of state tort law. The incentive structure is identical—and identically pernicious—in both contexts.[6]

* * *

Plaintiffs are attempting to do exactly what §337(a) and *Buckman* forbid. They are seeking to hold Ranbaxy liable in a private lawsuit for conduct that could be actionable *only* because it allegedly violated the FDCA's disclosure requirements. This suit is thus nothing more than a "proceeding[] for the enforcement . . . of" the FDCA, 21 U.S.C. § 337(a), and it cannot but undermine the careful balance Congress struck by permitting the Federal Government alone to police compliance with the FDCA. The Complaint should therefore be dismissed.

II. RANBAXY IS ENTITLED TO *NOERR-PENNINGTON* IMMUNITY.

Plaintiffs are attempting to hold Ranbaxy liable under the Sherman Act and the RICO Act because of the way in which Ranbaxy sought to influence the FDA's decisionmaking. But under the *Noerr-Pennington* doctrine, Ranbaxy's efforts to influence the FDA cannot trigger antitrust or RICO liability—even if Ranbaxy sought to influence the FDA by fraud, and even if such fraud did in fact influence the FDA to impose a restraint on Ranbaxy's competitors.

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[6] This Court previously noted that unlike in *Buckman*, here "the FDA has responded to Ranbaxy's [alleged] fraud by rescinding [tentative approval]," whereas in *Buckman* the FDA had not taken action in response to the defendant's alleged fraud. *Meijer I*, Dkt. 52 at 27-28. The Court observed that according to Justice Stevens—who did not join the majority opinion in *Buckman*—*Buckman* would have been "'a different case'" if the FDA had punished the defendants for defrauding it. *Id.* at 28 (quoting *Buckman*, 531 U.S. at 354 (Stevens, J., concurring in the judgment)).

Justice Stevens's separate writing of course cannot alter the scope and application of the majority opinion. *See, e.g.*, *Gill v. Whitford*, 138 S. Ct. 1916, 1931 (2018). In any event, while it is true that Justice Stevens said it should make a difference whether the FDA has responded based on its own finding of fraud, he *also* said that under the majority opinion, this distinction would make *no difference*. As he correctly recognized, "[u]nder the . . . analysis the Court offers today, . . . parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process." *Buckman*, 531 U.S. at 355 (Stevens, J., concurring in the judgment). Thus, far from helping the Plaintiffs here, Justice Stevens cogently explained why their Complaint must be dismissed.

Subject to narrow exceptions discussed below, antitrust laws do not apply to a market actor's attempts to influence government bodies, including administrative agencies. *See, e.g.*, *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965); *E. R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137-39 (1961); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Simply put, "[t]he federal antitrust laws . . . do not regulate the conduct of private individuals in seeking anticompetitive action from the government." *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 379-80 (1991). When anticompetitive effects flow from "'valid governmental action,'" the immunity of those urging the governmental action is "absolute." *Allied Tube*, 486 U.S. at 499. And *Noerr-Pennington* applies equally to RICO. *E.g.*, *Sosa v. DIRECTV, Inc.*, 437 F.3d 923, 931 (9th Cir. 2006); *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 826 (7th Cir. 1999); *see also Tomaiolo v. Mallinoff*, 281 F.3d 1, 11 n.9 (1st Cir. 2002).

Although Plaintiffs recognize that *Noerr-Pennington* potentially applies here, Compl. ¶¶ 311, 322, 362, they contend that Ranbaxy is not immune because it allegedly tried to influence the FDA through fraud, thus triggering the exception to *Noerr-Pennington* for "sham petitioning," *id.* ¶¶ 313, 324, 364. But Plaintiffs are wrong at every turn. First, petitioning activity is entitled to immunity even if it is fraudulent. And second, the "sham petitioning" exception does not apply here because Ranbaxy was genuinely seeking to convince the FDA to grant tentative approval to its ANDAs, and because any anticompetitive effects flowed from the FDA's *grant* of tentative approval, rather than from Ranbaxy's *petitioning* for tentative approval.

As an initial matter, petitioning activity is not stripped of its immunity simply because it is fraudulent. Indeed, *Noerr* itself held that immunity applied even though the defendant's attempt to influence government actors was "unethical," "deliberately deceived the public and public

officials," and was "fraudulent in that it was predicated upon the deceiving of [government] authorities." *Noerr*, 365 U.S. at 140, 145, 133. Likewise, *Omni* reiterated that "'deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned.'" 499 U.S. at 384. Going further, *Allied Tube* declared that "'[w]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy ***absolute immunity*** from antitrust liability for the anticompetitive restraint." 486 U.S. at 499 (emphasis added). That rule is dispositive here, because government action—such as the FDA's grant of tentative approval to an ANDA—is still "valid" under *Noerr-Pennington* even if it is induced by fraud, as *Noerr* held and *Omni* reaffirmed.

Moreover, petitioning activity does not lose its immunity even if it violates state or federal law. *Omni*, 499 U.S. at 381 (immunity applies notwithstanding that "manner" of petitioning is "improper or even unlawful"). The Supreme Court suggested that petitioning activity would not lose its immunity even if it procured government action through bribery, *id.* at 378, 382-84, and numerous Courts of Appeals have adopted that rule, *see, e.g.*, *Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 898 (10th Cir. 2011) (Gorsuch, J., on panel) (refusing to "carve out a special exclusion to *Noerr-Pennington* when the corruption involves . . . bribery or other acts that might violate state or federal law"). A different rule for fraud would make no sense. *Armstrong Surgical Ctr., Inc. v. Armstrong Cty. Mem'l Hosp.*, 185 F.3d 154, 162 (3d Cir. 1999) (explaining that under *Omni*, "[l]iability for injuries caused by . . . state action [that harms competition] is precluded even where it is alleged that a private party urging the action did so by *bribery, deceit or other wrongful conduct that may have affected the decision making process*" (emphasis added)).

Nor does the "sham petitioning" exception apply here, for two independent reasons. First, "[a] 'sham' situation involves a defendant whose activities are 'not genuinely aimed at procuring

favorable government action' at all, *not* one 'who genuinely seeks to achieve his governmental result, but does so through improper means.'" *Omni*, 499 U.S. at 380 (emphasis altered) (citation omitted). It is undisputed that Ranbaxy was genuinely trying to win tentative approval for its generic ANDAs—indeed, it succeeded in obtaining tentative approval for all three drugs at issue, and final approval for Diovan. These facts alone render the "sham petitioning" exception inapplicable. *Id.*; *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 n.5 (1993) ("A winning lawsuit is by definition . . . not a sham.").

Second, the sham exception applies only when a defendant "use[s] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *Omni*, 499 U.S. at 380. Here, Plaintiffs do not (and cannot) allege that Ranbaxy gained an anticompetitive advantage merely by *seeking* tentative approval; rather, Ranbaxy could benefit only after the FDA *granted* tentative approval. *E.g.*, Compl. ¶ 244 (explaining that Ranbaxy needed tentative approval "to monetize its first-to-file status"). Thus, as *Omni* put it, "the purpose of delaying a competitor's entry into the market does not render lobbying activity a 'sham,' unless . . . the delay is sought to be achieved only by the lobbying process itself, and not by the governmental action that the lobbying seeks." 499 U.S. at 381. That rule also precludes operation of the sham exception here.

III. THE COMPLAINT FAILS TO ALLEGE PROXIMATE CAUSATION.

Antitrust claims require proximate causation. *Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534-35 (1983). Thus, a suit must be dismissed if a plaintiff's "injuries were only an indirect result" of the defendant's conduct, or if they "may have been produced by independent factors." *Id.* at 541-42. And injury is not "antitrust injury" unless it "flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). RICO, too, requires a "direct relation" between the injuries and the misconduct alleged. *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992).

Plaintiffs' alleged injury is that they paid for expensive brand versions of Diovan, Nexium, and Valcyte when generic versions should have been available, but that generic versions were blocked from entering because Ranbaxy possessed 180-day exclusivities. *E.g.*, Compl. ¶ 289. Thus, to allege proximate causation, Plaintiffs must plausibly allege that Ranbaxy's supposed fraud on the FDA proximately caused it to possess exclusivity at a time when other generics were (or, absent Ranbaxy's alleged fraud, would have been) ready and able to come to market. The Complaint clearly fails to do so. First, while it may be true that Ranbaxy possessed exclusivity for a period of time for each of the drugs at issue here, Plaintiffs have *not* made plausible allegations that its possession of exclusivity was proximately caused by any fraud on the FDA. Rather, the Complaint itself and the documents it cites establish that fraud did *not* cause the FDA to grant, and to allow Ranbaxy to retain, its 180-day exclusivities for Diovan, Valcyte, and Nexium. Second, during the relevant time period—*i.e.*, while Ranbaxy still possessed exclusivity—Plaintiffs do not allege that *any other* manufacturer had obtained tentative approval (and was otherwise free to enter) for generic Nexium and Valcyte, which means that no manufacturer could have launched regardless of Ranbaxy's exclusivity. Both of these defects defeat proximate causation.

A. The Complaint Does Not Plausibly Allege that Ranbaxy's Possession of Exclusivity Was Proximately Caused by Fraud.

Plaintiffs' causal theory fails across the board because for each drug, there were three critical moments when the FDA decided that Ranbaxy was entitled to exclusivity, but Plaintiffs have not plausibly alleged that *any* of those decisions was proximately caused by fraud.

- Ranbaxy first became eligible for exclusivity when its ANDAs were deemed "substantially complete" by the FDA. Those decisions were not caused by fraud. *See* Compl. ¶¶ 180, 205, 219-220, 233; n.5 *supra*.

- Each drug cleared the next hurdle when the FDA granted it tentative approval. These decisions were also not induced by fraud. Although the Complaint repeatedly asserts otherwise in conclusory fashion, the only *facts* alleged in the Complaint make clear that the FDA has rejected that view. Even when the FDA later rescinded tentative approval

for Nexium and Valcyte, the FDA explained that "*the FDA . . . erred* in tentatively approving" the Valcyte and Nexium ANDAs. Compl. ¶¶ 222, 238 (emphasis added). In fact, the FDA has explained that it knew full well—"at the time of the tentative approval" decisions for both Valcyte and Nexium—that Ranbaxy's facilities were out of compliance with governing regulations. Schoen Decl., Ex. 4, at 11-12. Hence, "the FDA admits that granting tentative approval to the two ANDAs at issue was an error, which the [FDA] attribute[s] to a breakdown in communications between CDER, the compliance inspection component of the FDA, and OGD, the approval component of the FDA." *Ranbaxy Labs.*, 82 F. Supp. 3d at 190. In other words, fraud did not cause the FDA to grant tentative approval to the drugs at issue here. By contrast, the FDA *did* state that it granted tentative approval to Ranbaxy's Flomax ANDA based on fraud. Compl. ¶ 133 n.31. But nothing of the sort occurred for Diovan, Valcyte, or Nexium. Thus, the only non-conclusory allegations in the Complaint make clear that fraud did not proximately cause Ranbaxy to obtain tentative approval for the drugs at issue here.

- Finally—and most importantly—after becoming fully aware of Ranbaxy's misconduct, in 2010 the FDA considered requiring Ranbaxy to "immediately relinquish its claims to 180-day exclusivity for 16 different ANDAs," including "Diovan, Valcyte and Nexium." Compl. ¶ 170. But by 2012 the FDA decided that Ranbaxy could retain its exclusivity for Diovan, Valcyte, and Nexium. *Id.* ¶ 180. Nothing in the Complaint even hints that fraud played a role in this decision.

The upshot is that Ranbaxy possessed 180-day exclusivity because of three decisions made by the FDA, not one of which was proximately caused by fraud. For the three drugs at issue in this lawsuit, Plaintiffs' theory of proximate causation is therefore inadequate as a matter of law.

B. Plaintiffs Make No Allegation that Any Other Generic Had Obtained Tentative Approval for Nexium or Valcyte.

Plaintiffs' causal theory also fails, at least with respect to Nexium and Valcyte, because Plaintiffs make no allegation that any other generic not blocked by a patent had obtained tentative approval during the time Ranbaxy possessed exclusivity. Without such tentative approval, no other manufacturer could have entered the market, *regardless* of Ranbaxy's 180-day exclusivity.[7]

[7] Ranbaxy is aware that one manufacturer did obtain tentative approval for generic Valcyte in May 2014, *i.e.*, during the time Ranbaxy still possessed 180-day exclusivity. But the brand manufacturer still had patents over Valcyte, and the Complaint nowhere alleges that those patents did not still block generic applicants other than Ranbaxy from entering the market. While Ranbaxy's settlement with the brand manufacturer removed the patent block for *Ranbaxy* as of March 15, 2013, there is no allegation that the brand company holding the patents licensed any *other generic* to enter at any time during the period when Ranbaxy possessed exclusivity. Once again, the point is that other generics could not come to market for reasons having nothing to do with Ranbaxy's exclusivity.

Moreover, Plaintiffs do not (and cannot) plausibly allege that Ranbaxy's exclusivity proximately caused the FDA to withhold tentative approval from other generics. The very point of tentative approval is to signify that a generic is ready to launch but cannot because of "litigation or an exclusivity period." *Id.* ¶ 59. It is thus clear that Ranbaxy's exclusivity cannot have proximately caused a lack of generic Nexium or Valcyte. Plaintiffs cannot avert this pitfall by suggesting that "[i]t is . . . unknown what impact a forfeiture of Ranbaxy's first-to-file exclusivity would have had on the efforts of other generic ANDA filers seeking to bring generic Valcyte [or Nexium] to market." *Id.* ¶ 218; *see id.* ¶ 230. Such conjecture is inadequate because it does not even attempt to "nudge[] [Plaintiffs'] claims across the line from conceivable to plausible." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). It is also contradicted by the allegation that multiple generics obtained tentative approval for Diovan despite Ranbaxy's exclusivity for that drug. *Id.* ¶ 204. Anyway, it is not enough for Plaintiffs to allege that Ranbaxy's exclusivity was one of several "independent factors" that caused other generics to fail to obtain tentative approval. *Assoc. Gen. Contractors*, 459 U.S. at 542. *Holmes*, 503 U.S. at 269. Plaintiffs must plausibly allege that Ranbaxy's exclusivity was the *direct* cause of other generics' failure to launch. *Id.*; *Assoc. Gen. Contractors*, 459 U.S. at 540-41. Plaintiffs have come nowhere close to doing so.

IV. PLAINTIFFS' RICO CLAIMS FAIL FOR WANT OF A PREDICATE OFFENSE.

In addition to being barred by the FDCA and *Noerr-Pennington*, Plaintiffs' RICO claims fail because Plaintiffs cannot allege that Ranbaxy committed a predicate offense. Plaintiffs stake their RICO claims on the allegation that Ranbaxy committed "mail fraud in violation of 18 U.S.C. § 1341" and "wire fraud in violation of 18 U.S.C. § 1343." Compl. ¶¶ 332, 354. These allegations plainly fail because the mail and wire fraud statutes are both "'limited in scope to the protection of property rights.'" *Cleveland v. United States*, 531 U.S. 12, 18 (2000); *Pasquantino v. United States*, 544 U.S. 349, 355 & n.2 (2005). This rule means that "for purposes of the mail [and wire]

fraud statute[s], the thing obtained [by fraud] must be *property in the hands of the victim*." *Cleveland*, 531 U.S. at 15 (emphasis added). But here, the only thing Ranbaxy obtained from its victim—*i.e.*, the FDA—was "180-day exclusivities." Compl. ¶ 344. A license to 180-day exclusivity, however, is not by any stretch of the imagination "property" in the hands of the FDA.

Plaintiffs do not argue otherwise; nor could they, given *Cleveland*'s holding that government-issued entitlements such as "permits or licenses . . . do not rank as 'property,' for purposes of § 1341, in the hands of the official licensor." 531 U.S. at 15. Hence, both the mail and wire fraud statutes "do[] not reach fraud in obtaining a state or municipal license . . . , for such a license is not 'property' in the government regulator's hands." *Id.* at 20. The same is true here, for the FDA's "core concern" in granting exclusivity "is *regulatory*," and its "intangible rights of allocation, exclusion, and control amount to no more and no less than [its] sovereign power to regulate." *Id.* at 20, 23. Were there any doubt, Plaintiffs seal their fate by admitting that "the FDA sustained no damages to its business or property as a result of the fraud." Compl. ¶ 345. That admission is dispositive of their RICO claims. *Cleveland*, 531 U.S. at 15, 22; *Pasquantino*, 544 U.S. at 355, 357. To be sure, Plaintiffs allege that *they* lost money as a result of Ranbaxy's fraud on the FDA. But that allegation is relevant only to proximate causation; it does nothing to establish a predicate offense. And without a predicate offence, Plaintiffs' RICO claims must be dismissed.

CONCLUSION

The Consolidated Direct Purchaser Complaint should be dismissed in full, with prejudice.[8]

[8] Ranbaxy renews (and preserves for appeal) several arguments it briefed in full in *Meijer I*, including that Plaintiffs' causal theory fails with respect to Diovan because a change in the label's monograph insulated its exclusivity period from the FDCA's 30-month forfeiture deadline for obtaining tentative approval, Dkt. 48 at 4-8; that Plaintiffs fail to plausibly allege monopoly power, because Ranbaxy had a zero percent market share for each of the drugs at issue during the class periods, Dkt. 22 at 27-29; and that Plaintiffs cannot plead a RICO "enterprise," Dkt. 22 at 29-30, because "the unlawful enterprise itself cannot also be the person the plaintiff charges with conducting it," *Arzuaga-Collazo v. Oriental Fed. Savings Bank*, 913 F.2d 5, 6 (1st Cir. 1990), which is all the Plaintiffs have alleged. Ranbaxy would welcome the opportunity to re-brief these arguments, but in the interest of economy it relies on its previous briefs.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Laurence A. Schoen, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: May 31, 2019

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